Citation:

Villegas R, Liu S, Gao YT, Yang G, Li H, Zheng W, Shu XO. Prospective study of dietary carbohydrates, glycemic index, glycemic load and incidence of type 2 diabetes mellitus in middle-aged Chinese women. *Arch Intern Med.* 2007 Nov 26; 167 (21): 2,310-2,316.

PubMed ID: 18039989

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine associations between dietary carbohydrates, glycemic index (GI), glycemic load (GL) and carbohydrate-rich foods with the risk of type 2 diabetes mellitus in middle-aged Chinese women enrolled in the Shanghai Women's Health Study.

Inclusion Criteria:

- Resident of one of seven selected communities in Shanghai at baseline study recruitment (1996-2000)
- No history of cardiovascular disease, diabetes mellitus or cancer.

Exclusion Criteria:

Subjects who had extreme values for total energy intake (<500 or >3,500kcal per day).

Description of Study Protocol:

Recruitment

74,942 women aged 40-70 years at baseline from seven communities in Shanghai were recruited between 1996 and 2000.

Design

Population-based prospective cohort with follow-up every two years

Dietary Intake/Dietary Assessment Methodology

Food-frequency questionnaire (FFQ) (designed and validated for the population) with 77 items and

food groups that include 90% of foods commonly consumed in urban Shanghai during the study period.

Blinding Used

Not applicable.

Intervention

Not applicable.

Statistical Analysis

- Person-years were calculated as the interval between baseline recruitment and the diagnosis of type 2 diabetes mellitus, censoring at death or completion of the second follow-up
- Cox proportional hazards model was used to assess the rate ratio of type 2 diabetes mellitus by intake categories of carbohydrates, GI, GL and specific food groups
- Models were adjusted for socicodemographic variables and type 2 diabetes risk factors
- Stratified analysis was conducted by waist-hip ratio, body mass index (BMI) and physical activity categories, along with risk status for insulin resistance.

Data Collection Summary:

Timing of Measurements

- Dietary intake was assessed during the baseline survey and at the first follow-up survey two years later
- Incident type 2 diabetes mellitus was identified through follow-up surveys every two years.

Dependent Variables

- Type 2 diabetes: Confirmed diagnosis included participants reported having been diagnosed as having type 2 diabetes and met at least one of the following criteria:
    - Fasting glucose level ≥126mg/dL on two separate occasions
    - Oral glucose tolerance test value ≥200mg/dL
    - Use of a hypoglycemic medication
- Other subjects who self-reported having type 2 diabetes were considered to have probable type 2 diabetes. Results are presented with all cases combined because similar results were obtained with separate analyses.

Independent Variables

- Glycemic load: The glycemic load of each food was calculated by multiplying the carbohydrate content of each food by the food's GI value and the average amount of food consumed per day. These products were then summed over all foods to produce the dietary GI
- Dietary glycemic index: Divided the dietary GL by the amount of carbohydrate intake.

Control Variables

- Age
- Level of education
- Family income
- Occupation

- Smoking status
- Alcohol consumption
- Non-occupational physical activity
- Hypertension diagnosis.

Description of Actual Data Sample:

- *Initial N:* 74,942 in cohort at baseline
- *Attrition (final N):* 64,191 (excludes those without follow-up; with a history of chronic disease; and with improbable dietary values)
- *Age:* 40-70 years at baseline
- *Ethnicity:* Chinese
- *Other relevant demographics:* Participants in the higher quintiles of GL were more likely to be older, less educated, have a lower annual income, be housewives or retired, to have ever smoked, and less likely to exercise and to have ever consumed alcohol
- *Anthropometrics:* Percent of participants in quintiles of GL who had a BMI≥30kg/m^2 ranged from 2.9 to 7.4%.
- *Location:* Shanghai, China.

Summary of Results:

Association of Carbohydrate Level, Glycemic Undex, Glycemic Load and Food Groups with High-glycemic Index with Risk of Type 2 Diabetes

Dietary Data	Relative Risk[a] (95% CI)
Carbohydrates[b]	
Q1	1 (reference)
Q2	0.96 (0.80, 1.15)
Q3	0.87 (0.73, 1.05)
Q4	1.09 (0.92, 1.29)
Q5	1.28 (1.09, 1.50)
Glycemic index[b]	
Q1	1 (reference)
Q2	1.04 (0.87, 1.24)
Q3	1.02 (0.86, 1.22)
Q4	1.09 (0.92, 1.29)
Q5	1.21 (1.03, 1.43)
Glycemic load[b]	

Q1	1 (reference)
Q2	1.06 (0.88, 1.27)
Q3	0.97 (0.81, 1.17)
Q4	1.23 (1.03, 1.46)
Q5	1.34 (1.13, 1.58)
Staple food items[c]	
Q1	1 (reference)
Q2	1.13 (0.94, 1.35)
Q3	0.96 (0.80, 1.16)
Q4	1.13 (0.94, 1.37)
Q5	1.37 (1.11, 1.69)
Rice (g per day)	
>200	1 (reference)
200-249	1.04 (0.86, 1.25)
250-299	1.29 (1.08, 1.54)
≥300	1.78 (1.48, 2.15)

Q = quartile

[a]: Adjusted for age, kcal per day consumed, BMI, waist-hip ratio, smoking status, alcohol consumption, physical activity, income level, education level, occupation, diagnosis of hypertension

[b]: Energy-adjusted

[c]: Rice, noodles and steamed bread and bread

Key Findings

High carbohydrate intake, dietary GI and GL and a high intake of staples (and rice) were associated with an increased risk of type 2 diabetes (see Table).

Other Findings

- During a average of five years of follow-up (297,755 person-years), 1,608 incident cases of type 2 diabetes documented
- The percentage of energy contributed by carbohydrates (Q5 vs. Q1) was associated with an increase in the risk of type 2 diabetes RR=1.31 (95% CI: 1.10, 1.50).
- The effect of carbohydrate intake, GI, GL and rice intake increasing the risk of type 2 diabetes was slightly stronger in participants with higher WHRs and higher BMI
- The association of carbohydrate intake, GI, GL and rice intake with type 2 diabetes seemed to be more pronounced in participants with low activity levels.

- Carbohydrate intake, glycemic load and rice intake were more strongly related to the risk of type 2 diabetes in subjects with a high risk of insulin resistance (participants having WHRs >0.85, BMI >25kg/m^2, and being in the lower quartile of physical activity METs).

Author Conclusion:

- Carbohydrate intake, staple foods (rice in particular), glycemic index and glycemic load were all positively associated with the risk of type 2 diabetes in a large prospective study of middle-aged Chinese women
- The authors note that dietary patterns in Shanghai are different from those in the Western world (in Shanghai, rice is a main staple food, whereas potatoes are consumed in lower amounts).

Reviewer Comments:

Author-identified limitation: A longer follow-up time would provide more statistical power to verify findings.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	???
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	N/A
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes